July 2003

Minnesota Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

University Park Plaza
2829 University Ave SE, Suite 530
Minneapolis, MN 55414-3251
www.phcybrd.state.mn.us

Disciplinary Actions

The following disciplinary actions were taken by the Minnesota Board of Pharmacy during the three-month period of March, April, and May of 2003.

Jonas, Daniel T., License No. 114380-1. The Board alleged violations of a previous order of the Board dated July 25, 2001. In response to these allegations, the licensee has agreed to discontinue the practice of pharmacy in the state of Minnesota. The licensee may petition for authorization to resume the practice of pharmacy not earlier than October 15, 2003. Upon authorization to resume practice, licensee will be placed on probation with the Board.

Warren, Todd A., License No. 115324-4. Licensee was convicted of a crime that occurred on the premises of his pharmacy. Licensee's personal license to practice pharmacy in Minnesota was suspended for a period of 90 days effective May 14, 2003. Upon the reinstatement of his license to practice pharmacy, the licensee will be placed on probation with the Board.

Program for Destruction of Unused Chemicals Established

It has come to the Board's attention that a number of Minnesota pharmacies have supplies of old chemicals and bulk drugs previously used in compounding in their possession. Proper disposal of these chemicals is a difficult issue for many pharmacists to address.

The Minnesota Board of Pharmacy, in conjunction with the University of Minnesota, is offering a pharmacy hazardous waste collection program for pharmacies in the state of Minnesota through the University's Chemical Safety Day Program (CSDP).

The Chemical Safety Day Program (www.dehs.umn.edu/csdp) is a cost-effective waste management program available to educational institutions, nonprofit organizations, and government agencies throughout the state of Minnesota. In cooperation with the Board of Pharmacy, the university is able to offer this service to participating pharmacies as well. The CSDP works under the State Hazardous Waste Contract and tailors the program to each customer's specific needs. Collective waste is processed at the Integrated Waste Management Facility (IWMF) at the University of Minnesota – Twin Cities Campus. Ninety percent of the waste processed at IWMF comes from the university system and 10% is collected from schools, institutions, and agencies through the CSDP.

All participants are required to have a federal "Environmental Protection Agency (EPA) Identification (ID) Number" and a hazardous waste generator license in order to participate in the Pharmacy Hazardous Waste Collection Program. Check your records to see if your pharmacy already has a federal EPA ID Number or generator license. If you do not, or are not sure, call the Minnesota Pollution Control Agency for assistance at 1-800/657-3864 or 651/297-8360.

To participate in the program, a pharmacy needs to prepare an inventory of chemicals that need to be disposed. The inventory must include the name of the chemical compound (or compounds and percent composition if a mixture), the amount of the compound in the container, and the number of containers of the same compound.

Inventories are submitted to the University of Minnesota for review and initial processing. After the University of Minnesota reviews the submissions, pharmacies are notified of the dates and times of a pre-collection visit, if one is necessary. This pre-collection visit is used to properly package the chemicals, label containers, and, if necessary, answer any unresolved issues. The actual collection occurs one or two weeks later with pharmacies being notified of the dates and times. The CSDP prepares all necessary regulatory paperwork and comes directly to your site for the collection. Pharmacies are not involved in any transportation. The CSDP transports the material/waste to its permitted IWMF (a fully permitted storage facility) for processing. By submitting inventories, a pharmacy is not obligated to participate in the program, just as the University of Minnesota is not obligated to accept a pharmacy's material/waste.

The participants pay for the costs of the Pharmacy Hazardous Waste Collection Program. For last year's CSDP, the average disposal cost was about $12 per kilogram. The disposal cost for any particular item ranged from approximately $5 to $60 per kilogram. There is a minimum charge of $.50 per chemical container and $50 per customer. An estimate is provided prior to scheduling the actual collection to make sure a pharmacy still wishes to participate. After the actual collection and processing, the pharmacy is billed for the quantity of material/waste received. Invoices are mailed out within 60 days after the collection. A detailed description of how material/waste was processed is provided.

Further information, such as a tentative 2003 schedule, chemical information, and pricing details, can be obtained by visiting the CSDP Web site at www.dehs.umn.edu/csdp or contacting CSDP Manager Andrew A. Kimball: phone 612/626-1553; fax 612/626-1571; e-mail kimba013@umn.ed.

Substitution of Isotretinoin

Questions have arisen regarding the substitutability or nonsubstitutability of Accutane® with other branded generics of isotretinoin.

Since there are significant and detailed educational and certification issues associated with the dispensing of isotretinoin products, and since some of the educational and certification issues

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FDA Issues Draft Guidance on Potassium Iodide Shelf Life Extension

Food and Drug Administration (FDA) has issued a draft guidance entitled, "Guidance for Federal Agencies, and State and Local Governments – Potassium Iodide Tablets Shelf Life Extension," on how to conduct drug testing to determine the shelf life of stockpiled potassium iodide (KI) tablets.

A number of state and local governments maintain stockpiles of KI tablets for use in a radiation emergency involving the release of radioactive iodine. Several states have asked FDA how to determine whether stockpiled KI tablets have retained their original quality after passing the expiration date. The methods listed in this guidance could verify the continued viability of these drugs when stored under controlled conditions.

FDA, working with other federal agencies and state and local governments that stockpile KI tablets for use in the event of a radiation emergency, is providing guidance on how to conduct shelf life testing and how to identify laboratories that are suitable for conducting shelf life extension testing. The FDA draft guidance also provides information on how to notify holders of stockpiled KI tablets about changes in shelf life and how to distinguish stockpiled batches with different shelf lives.

FDA Proposes Labeling and Manufacturing Standards for All Dietary Supplements

On March 7, 2003, Food and Drug Administration (FDA) proposed a new regulation to require current good manufacturing practices (CGMPs) in the manufacturing, packing, and holding of dietary supplements.

The proposed rule includes requirements for designing and constructing physical plants, establishing quality control procedures, and testing manufactured dietary ingredients and dietary supplements. It also includes proposed requirements for maintaining records and for handling consumer complaints related to CGMPs.

According to FDA, in recent years, analyses of dietary supplements by a private sector laboratory suggest that a substantial number of dietary supplement products analyzed may not contain the amounts of dietary ingredients that would be expected to be found based on their product labels. For example:

- Five of 18 soy and/or red clover-containing products were found to contain only 50% to 80% of the declared amounts of isoflavones.
- Of 25 probiotic products tested, eight contained less than 1% of the claimed number of live bacteria or the number of bacteria that would be expected to be found in such a product.

FDA has also encountered products being marketed that are not accurately labeled or contain contaminants that should not be present or may be harmful. For example:

- One firm recalled its dietary supplements that were contaminated with excessive amounts of lead, which may have posed a health risk to many consumers, especially children and women of childbearing age.
- Another firm recalled a niacin product after it received reports of nausea, vomiting, liver damage, and heart attack associated with the use of its product. A dietary ingredient manufacturing firm had mislabeled a bulk ingredient container that subsequently was used by another firm in making a product that contained almost 10 times more niacin than the amount that may be safe.

This proposed regulation follows FDA's consumer initiative announced last December and intended to improve the agency's policies on providing information about health consequences of food and dietary supplements as well as increase enforcement efforts to prevent misleading health claims made by certain dietary supplement manufacturers.

Under the CGMP proposal, manufacturers would be required to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated. Some product quality problems the CGMPs would help prevent include products that are superpotent or subpotent; that contain the wrong ingredient, a drug contaminant, or other contaminants (eg, bacteria, pesticide, glass, and lead); that contain foreign material; and that are improperly packaged and mislabeled.

This proposal is intended to cover all types of dietary supplements. However, to limit any disruption for dietary supplements produced by small businesses, FDA is proposing a three-year phase in of a final rule for small businesses. The proposal includes flexible standards that can evolve with improvements in the state of science, such as in validating tests for identity, purity, quality, strength, and composition of dietary ingredients.

FDA is soliciting comments from the public and industry on how this proposed regulation can best achieve the goals of promoting accurate labeling information and preventing adulteration without imposing unnecessary regulatory burdens. Written comments will be received until 90 days after the date of publication in the *Federal Register* and may be addressed to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Ln, Room 1061, Rockville, MD 20852.

Study Finds Dispensing Errors a National Problem

A national observational study of prescription dispensing accuracy and safety in 50 pharmacies recently published in the *Journal of the American Pharmacists Association* (*JAPhA*) found that dispensing errors are a problem on a national level. The study found a rate of four errors per day in a pharmacy filling 250 prescriptions daily; an estimated 51.5 million errors occur during the filling of three billion prescriptions each year.

Data was collected by a team of observers between July 2000 and April 2001 from chain, independent, and health-

system pharmacies in six large United States cities. An observing pharmacist was present in each pharmacy for one day with the goal of inspecting 100 prescriptions for dispensing errors (defined as any deviation from the prescriber's order). Overall, the dispensing accuracy rate was 98.3%, or 77 errors among 4,481 prescriptions. Of the 77 identified errors, 6.5% (five) were judged to be clinically important.

Taking these results into consideration, the researchers hypothesize that the typical pharmacist will incorrectly fill two new prescriptions each day (based on a workload of 60 new prescriptions). The most common errors that will occur is giving the wrong instructions for use, but may also include dispensing the wrong drug, wrong strength, or wrong quantity. The complete study can be found in the March/April 2003 issue of the *JAPhA*.

Is Your Pharmacy in Danger of Missing the Point About Levothyroxine?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Physician confusion about decimal point placement with levothyroxine doses is a commonly reported problem. For example, we frequently hear about errors where prescribers have ordered levothyroxine 0.25 mg instead of the correct dose of 0.025 mg. Imagine the consequences if an elderly woman with a cardiac condition accidentally received ten times the dose of levothyroxine that was intended? Another source of error is related to converting the dose from micrograms to milligrams. Mathematical errors and decimal point misplacement have been reported often, especially if the conversion occurred mentally. We have also heard about errors when converting oral therapy to IV doses in the hospital. The bioavailability of oral products is only 50%, but it is 100% for IV doses. Sometimes the need to cut back on the IV dose goes unrecognized.

Because errors are so common with this drug, one pharmacist told us that his pharmacy set up their computer to alert whenever a 0.25 mg dose is entered. When the warning appears, the correct dose almost always has been 0.025 mg. Just days after he commented, the same pharmacist received an order for levothyroxine 0.75 mg PO daily. Upon checking the patient's drug history from a prior admission, he noticed that the patient had been taking 0.075 mg. While someone with experience may realize that 0.75 mg is an excessive amount, orders for 0.25 mg could slip by more easily. After all, levothyroxine is available in a 0.3 mg tablet strength, although Facts and Comparisons mentions that the dose for hypothyroidism rarely should exceed 0.2 mg.

Pharmacists must recognize the risks associated with dosing this product and provide feedback directly to prescribers if an excessive dose is suspected. Avoid decimal points and dose conversions by encouraging prescribers to order the medication the same way that manufacturers express the dose – in micrograms, not milligrams. Since levothyroxine has a half-life of around seven days, hospital pharmacists should remind prescribers that it probably is unnecessary to change an oral dose to IV unless the patient is NPO for several weeks. Program computer systems to alert if the dose exceeds 200 mcg (0.2 mg) daily. Finally, consider shelf labels to remind staff to check, if higher doses are prescribed.

Beware of Mistaking Aripiprazole (ABILIFY) for a Proton Pump Inhibitor (PPI)

Aripiprazole is an antipsychotic agent used to treat schizophrenia, but potential name confusion with drugs in the proton pump inhibitor class has been reported since FDA approved the drug last November. The thought may arise because the drug's generic name ends with "prazole," which is similar to the name stem used within the PPI class such as omeprazole (PRILOSEC), esomeprazole (NEXIUM), rabeprazole (ACIPHEX), lansoprazole (PREVACID), and pantoprazole (PROTONIX). Also, dose ranges for Abilify (10-30 mg daily) are similar to PPIs, and Abilify is available in 10, 15, 20, and 30 mg tablets, which overlap with the 10-40 mg range of strengths available with PPIs. The importance of knowing indications, doses, and adverse effects of unfamiliar medications prior to ordering, dispensing, or administering them cannot be understated.

Be MedWise Kit Now Available

To promote the wise use of over-the-counter (OTC) medicines, the National Council on Patient Information and Education (NCPIE) recently launched a nationwide consumer education campaign called *Be MedWise*. The goal of the campaign is to ensure that consumers understand that OTC products are serious medicines that must be taken with care.

NCPIE, a coalition of consumer, health care professional, voluntary health, government, and industry members, found evidence for the creation of such a campaign in a study by Harris Interactive®, which found that 59% of Americans use OTC medicines routinely, but only 34% can name the active ingredients in the products they are using. The *Be MedWise* tool kit was designed to help health care providers, consumer and patient groups, professional organizations, and government agencies correct this statistic. The tool kit contains a news release; three informative columns or publication inserts; a full-page public service print ad to be used as a flyer or poster; a brochure; logos; and special event ideas. Many of these resources are available for download on www.bemedwise.org.

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are product specific, it is the position of the Board that pharmacists should not exercise their prerogative of substitution when it comes to isotretinoin products.

Medication Errors Continue to be an Issue

Medication errors in Minnesota continue to be an issue, as they are nationwide. In its April 2003 *Newsletter*, the Nevada State Board of Pharmacy also addressed this issue. Since the scenarios described in the Nevada article are the same issues that Minnesota has faced, it is appropriate to reiterate the Nevada article for this *Newsletter*.

> In February 2003, the Nevada [State] Board of Pharmacy faxed a broadcast alert notice resulting from two consumer complaints by the survivors of patients in which morphine sulfate solution (20 mg/ml) was allegedly mislabeled by the pharmacy.
>
> Whether the subsequent overdoses caused or were contributory to the patients' deaths is under investigation. Most important to this agency, and hopefully to every practicing pharmacist, is the question: How does a concentrated morphine solution leave the pharmacy labeled incorrectly?
>
> Here are some rhetorical questions you might consider in your practice:
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> - Are the speed codes for sigs easily confused between directions for milliliters and teaspoonfuls?
> - Does your computer system have a high-dose alert that cannot be overridden by a clerk or technician's single keystroke?
> - Does a high-dose alert cause a computer to do a hard stop?
> - When a manufacturer's recommended dosage is in milliliters, will your computer create a stop requiring a pharmacist override if a teaspoonful or a larger quantity dose is typed into the sig?
> - Does your pharmacy acknowledge and address the most common drugs causing death or injury to patients? For example, Nevada's top two are morphine and Coumadin®. Are the products placed in special storage for special handling and review? Could they have a caution sleeve covering or be in a box to alert special consideration?
> - Are pharmacists too comfortable with their clerk's or technician's work and are, thus, not checking their work as diligently as they should?
> - Has your double-, triple-, or quadruple-check system emphasized the product contents and not the directions?
>
> During a quality assurance discussion in your pharmacy, you might consider these or other systems to prevent medication errors. Pharmacists have repeatedly expressed their chagrin for allowing an uncomplicated medication error. Nobody – not the patient, the physician, the pharmacist, or the Board – wants even one more medication error, so please examine your pharmacy to determine what might be done to prevent the next error from being in your pharmacy.

June Board Exam Information

The Board of Pharmacy offered the "Practical" portion of the Board examination for new graduates on June 10, 2003. The total examination experience for new graduates is composed of three different examinations, two of which are "national" exams and are scheduled individually by each candidate for licensure. The third examination is the Board's Practical.

It appears that approximately 180 candidates sat for the Board's Practical Examination in June. This number is down only slightly from last year's record of 187.

Pharmacists who will be employing new graduates are cautioned not to schedule them for work as a pharmacist until they have been shown a copy of the letter from the Board of Pharmacy indicating that the candidate has successfully passed the exam and is now licensed. Licensure requires that the candidate pay the original licensure fee in addition to passing the examinations.

Pass/fail letters are generally sent to the candidates within 10 days of the Board receiving the last of the three exam scores. Since exam candidates make their own appointments to sit for the two computerized portions of the exam, the pass/fail letters do not all go out at the same time.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

David E. Holmstrom, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Reneeta "Rene" Renganathan - Editorial Manager

MINNESOTA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
700 Busse Highway
Park Ridge, Illinois 60068

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